

# CriticalValues

News for the Entire Laboratory Team

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*Matt F.*

Roche, USA



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# Health Services RESEARCH



E. Blair Holladay, Ph.D., SCT(ASCP)<sup>CM</sup>

studies, so we ensure patients receive high quality care delivered in a cost-effective manner.

In keeping with the ascribed emerging area of evidence-based practice, the ASCP is delighted to announce the development of the Center for Health Services Research (CHSR). Through the CHSR, the ASCP will develop programs that will allow our members to proactively position themselves within the clinical setting by assisting in both diagnostic test selection and advising in clinical therapeutics. In addition, the ASCP intends to provide professional development offerings that are patient-centric in nature.

The development of the CHSR within the ASCP is currently under way. Over time, the CHSR will also provide a mechanism for members to engage in studies of best practices, help us ensure our international outreach activities are geared toward evidence-based practice, and assist our

*“Science is built up of facts, as a house is built of stones; but an accumulation of facts is no more science than a heap of stones is a house.”*

~Henri Poincaré, *Science and Hypothesis*

Science begins with an amalgamation of data. In relation, the measure of any gold standard laboratory test should be based on data-driven scientific quality, as well as clinical proof of an improved outcome. In an age of soaring healthcare costs, it is rapidly becoming an imperative to offer patients high-quality tests that have been proven to improve the patient's outcome, while at the same time, to ensure their safety.

Our profession has an ethical responsibility to reduce healthcare costs by determining which laboratory tests fit within this scientific paradigm and offer those assays that prove most efficacious. Unfortunately, often the strings tethered to “new or improved” laboratory assays are not associated with enhanced clinical outcomes.

Often at issue is not which test is best, but how many tests can be performed within any given disease profile, despite their lack of relational clinical utility. As a result, treatment for patients is often inconsistent and based on professional experience rather than data-driven evidence.

Does the mere existence of a newly marketed “sensitive and specific” test—even in the absence of longitudinal studies necessary to prove its clinical utility—provide sufficient merit for laboratory practitioners to recommend that clinicians order that test for the patient? Pathology and laboratory medicine must transition toward evidence-based practice to ensure we meet the needs of our patients.

A key factor for improving our current practice paradigm lies within the field of health services research. Ultimately, it will be up to our profession to recommend the most effective laboratory assays (and clinical solutions) by performing the necessary research that comparatively analyzes the basic, clinical, and translational

profession by providing data-driven, scientifically validated practice guidelines. In 1999, ASCP past President Lee H. Hilborne, MD, MPH, FASCP, DLM(ASCP)<sup>CM</sup>, suggested that health services research in pathology and laboratory medicine was “coming of age.” Although the field has taken longer to develop than he anticipated, the articles in this edition of *Critical Values* indicate that health services research in pathology and medicine is poised to make its debut on the health care landscape.

I am pleased this issue of *Critical Values* has chosen to focus its attention on the area of health services research with informative articles by Dr. Hilborne, Paul Chiou, CT(ASCP), and Susan R. Snyder, PhD, MBA. Each of these diverse scientific experts brings a unique and critical understanding to the ASCP's decision to embark upon and embrace this new enterprise. Our members are our most valued source, and we hope each of you enjoy this important issue.

Lastly, if you would like to learn more about ASCP's Center for Health Services Research, please feel free to contact me directly at [blair.holladay@ascp.org](mailto:blair.holladay@ascp.org). We look forward to continuing to serve you as the oldest and largest medical society representing pathologists and laboratory professionals within the United States.

*“The scientist is not a person who gives the right answers, but rather the one who asks the right questions.”*

~Claude Lévi-Strauss, *Le Cru et le cuit*

*Dr. Holladay is Executive Vice President of ASCP.*

# Critical Values

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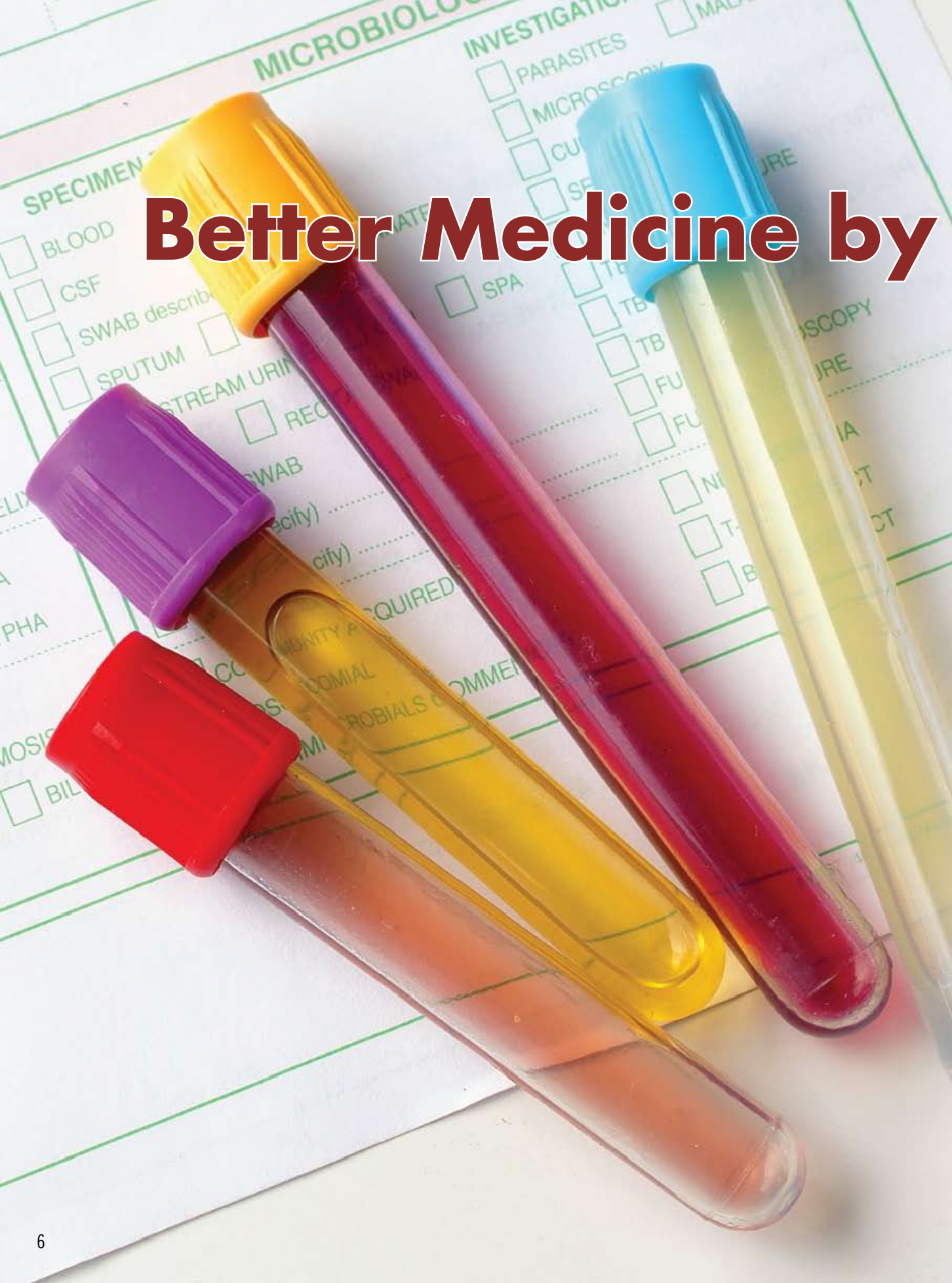
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In this issue



# Better Medicine by





# Customizing Health Care

By John E. Tomaszewski, MD, FASCP



Tomaszewski

As medicine becomes increasingly sophisticated, the decisions that we make about what diagnostic tests to do and which therapeutic options to choose become more critical. The good news is that sophisticated technologies make more accurate and thorough diagnoses possible. This translates into better therapeutic choices. The bad news is that as we become more “high-tech,” mistakes and poor choices become more costly. Mistakes cost patients time and money—possibly even pain and suffering. Our challenge is to help clinicians and patients make good choices about which diagnostic tests to use and which therapies to employ from the outset. But, exactly how do we do this? Some promising new options are coming to the fore through the use of personalized medicine and health services research.

## Tailor-Made Medicine

The term *personalized medicine* is used in several ways. One connotation involves the use of molecular tests to predict an individual patient’s response to a particular therapy. A second type is *therapeutic cellular engineering*. This involves harvesting the patient’s own cells, modifying genes in those cells for a therapeutic effect, and then infusing the modified cells back into the patient as a disease treatment.

A third kind of personalized medicine, and the one most pertinent to laboratory professionals and diagnostics, is *integrated diagnostics*. It involves the incorporation of data from multiple diagnostic technologies to provide a unique and extremely accurate prognostic and predictive diagnosis, one specific to each patient. The most useful data for integrated diagnostics come from the clinical labs, and right now the volume of this information is exploding.

The pace of new test development is driven by the ongoing technological revolutions in molecular biology and imaging science. New diagnostic modalities only dreamt of a few years ago are now being introduced into clinical practice. Precise molecular and imaging data will soon be available in previously unimaginable quantities.

Integrated diagnostics does present some challenges. One is the difficulty inherent in dealing with large sets of multidimensional data. This means digesting and evaluating a huge volume of complex information. The advantage of multidimensional data is that all the pertinent information needed for an accurate diagnosis, prognosis, or therapeutic prediction is captured. Multidimensional data also offer us multiple pathways or routes for reaching the desired outcome. Unfortunately, not every pathway is equally effective, so we have to determine which of the routes is best. It is likely that computers and specialized software will become important tools for helping to make good choices.



## The Need for More Research

Another promising area of activity is health services research. This is a multidisciplinary field of scientific investigation that examines how various medical technologies, economics, organizational processes, social factors, and personal behavior affect the quality, effectiveness, and cost of health care as well as patient access to that care.

Health services research is data-driven and focuses on clinical outcomes. A variety of methodologies can be employed in health services research. One is comparative effectiveness research (CER). According to the Institute of Medicine, CER is “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.”

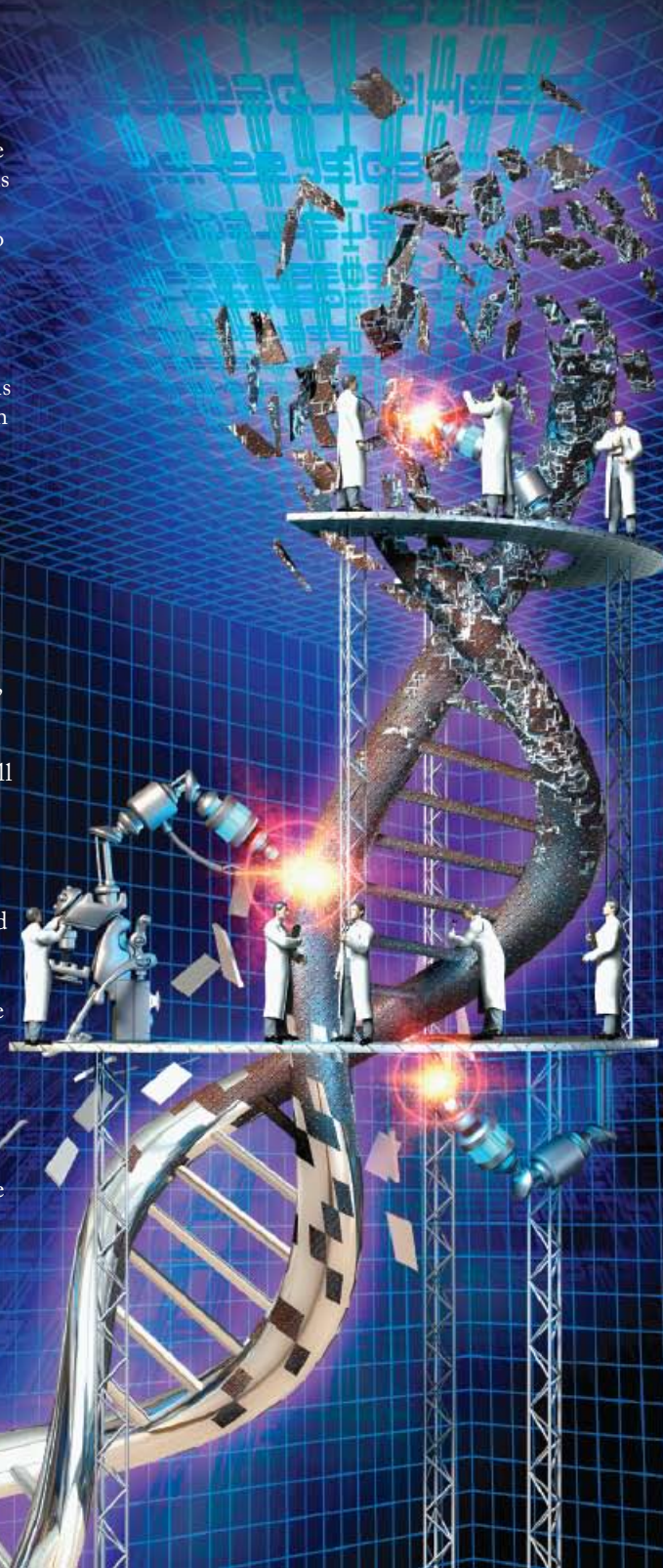
I believe that the value of diagnostic testing for improving clinical outcomes is underappreciated. CER is a good way to demonstrate its efficacy, but more research is needed.

ASCP plans to encourage its development by establishing a Center for Health Services Research (CHSR) under the umbrella of the ASCP Institute. The goal is to pursue a multidisciplinary research agenda funded by extramural grants and contracts. We hope to provide information that will assist pathologists and clinicians in selecting the best diagnostic tests and therapeutic options. I believe CHSR will put ASCP, and, by extension, the profession at the center of healthcare decision-making and enable pathologists to have a primary influence on patient care. The work of CHSR will also provide valuable information for the development of new ASCP educational offerings.

The ASCP Task Force on Transition identified patient-centered advocacy as the best way to achieve the Society's primary mission. The Board of Directors accepted the task force recommendation to focus ASCP resources and efforts in that direction. Health services research is congruent with patient-centered advocacy. Scientists in the pathology and laboratory medicine community generally focus on the biomedical and clinical aspects of health services research. CHSR will give ASCP the opportunity to expand clinical pathology and laboratory medicine research into the broader field of evidence-based practice. Through this initiative ASCP hopes to proactively help the medical profession reduce healthcare costs. We will do it by using data-driven best practice guidelines for pathology and laboratory medicine to increase the effectiveness and efficiency of patient care.

I welcome your comments and questions. Please e-mail them to me at [President@ascp.org](mailto:President@ascp.org).

*Dr. Tomaszewski is Professor and Interim Chair of the Department of Pathology and Laboratory Medicine at the University of Pennsylvania, Philadelphia.*







## Message from the Chair of the Council of Laboratory Professionals



Harris

By Teresa Harris, MT(ASCP)SBB, CQIA, CQA(ASQ)

# CAREER OPTIONS

## for Laboratory Professionals

**W**hen I started medical technology school way back in the 1970s, I had no idea where my career would lead me. Looking back, I realize I was pretty naïve and not very well informed about my chosen career path. I thought medical technologists/medical laboratory scientists worked only in hospitals. As my career progressed, I discovered this was not the case. Not only were there a multitude of career paths available to me, there was also a lot of variety in the types of jobs out there.

My own career path took me, first, to a small rural hospital (15 beds), then to a physician clinic and then to a blood center. For much of my career, I worked for a highly specialized immunohematology reference laboratory as a bench technologist and, later, as a laboratory manager. I have also worked for several years as an independent consultant. Right now I provide operational support to a number of laboratories that serve a large blood provider, a job that allows me to work “virtually” from my own home.



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## Opportunity Abounds

Occasionally I hear laboratory professionals complain that their careers lack growth potential and opportunity. I disagree. In fact, I believe laboratory career opportunities are extensive—even expanding. There continue to be a wide range of positions for laboratorians within the traditional hospital setting, including bench staff, lead staff, supervisors, managers, directors, technical specialists, information technology specialists, safety specialists, and quality assurance specialists, just to name a few. But, it is also a good idea to look beyond hospital walls.

There are also many nontraditional work settings that provide jobs to certified laboratory professionals. And some of these jobs are very different from those found in hospitals. These nontraditional work settings include, but definitely are not limited to, reference laboratories, research laboratories, blood centers, consulting firms, and inspection and assessment agencies like ASCP and The Joint Commission.

Those interested in sales or product development should also consider jobs with commercial companies that develop and sell equipment and supplies to clinical and research laboratories. Independent consulting is another viable option for those who have the necessary experience and personal qualities.

Right now, the economic climate is creating jobs in new fields like outcomes healthcare research. This movement is driven by a continuing decline in healthcare dollars and subsequent attempts to rein in spending without adversely affecting patient outcomes. The outcomes research arena is a prime opportunity for clinical laboratory professionals to step outside laboratory walls and use available laboratory data to develop protocols and provide information that can cut costs without reducing the quality or effectiveness of patient care.

Certified laboratory professionals are well suited for these kinds of research initiatives. We are problem solvers by nature and, in many ways, “data crunchers.” You can start out by determining whether any outcomes research is going on in your own facility. If it is, you can try to get involved. If you find no initiatives at your facility, perhaps you can help initiate one. I believe your efforts will be rewarded in both the short- and long-term. If nothing else, it will help you build communication with other hospital teams.

## Strategies for Leadership Development

There are actually many certified laboratory professionals who have become chief executive officers (CEOs) or moved into other executive management positions. It didn't happen overnight. Many upper management positions require additional certifications, training, or education, but the same is true for those working in any other field of endeavor. This is why ASCP offers a Diplomate in Laboratory Management certification for those who want to become laboratory managers, directors,

or CEOs. Likewise, a Specialist in Blood Banking certification is often a useful credential for blood center managers and directors.

Opportunity is there for those who seek it; but it probably won't come to fruition without commitment and effort on your part. Don't sit around waiting for opportunity to knock. Instead, stretch your boundaries and invest in developing new tools and capabilities. This kind of personal growth will help prepare you to take on new responsibilities and challenges when they present themselves.

The exact path you take is up to you. There is any number of steps you can take to add to your skill set and better position yourself to take advantage of future opportunities. Some steps are relatively simple, while others require more time and effort. You might decide to work toward a specialist certification, get an MBA, volunteer for a project team, reach out to a speaker about how to improve something in your laboratory, improve your speaking skills and self-confidence by belonging to organizations like Toastmasters, join a local laboratory professional group, or become a local ASCP representative. Whatever path you follow, the journey begins with the first step. The only way to really fail is to not try in the first place.

I'd love to hear about your experience. Send me an e-mail at [MemberChair@ascp.org](mailto:MemberChair@ascp.org).

*Ms. Harris is Senior Associate, Biomedical Headquarters, Immunohematology Reference Laboratories, Biomedical Services, at the American Red Cross, Winthrop, WA.*





# Leadership Messages

Message from the Co-chairs of the Resident Council

By Jessica A. (Wieberg) Kozel, MD

# Preparing for



Illustration: Tom Payne





Kozel

# Your Future Dream Job

**W**hen I was trying to decide on a medical specialty, one of the things that appealed to me about pathology was its diversity. Pathology has more varied career tracks than almost any other medical field. The pathology faculty at my own institution exemplifies a myriad of distinct career paths, all of which lead to successful roles within our hospital system. Some individuals have obtained PhD training and work half time doing research. Some are faculty members who practice solely in anatomic pathology while others practice transfusion medicine exclusively. Some individuals have tenure-track positions, and others are clinical instructors. The more one looks around, the more possibilities one sees.

In addition to diverse career choices, pathology also offers a variety of routes for getting the training and expertise needed for your final “dream” job. Most residents pursue fellowships. Others combine primary certification and subspecialty training residencies, such as an anatomic pathology/neuropathology residency. Although there is a

plethora of practicing pathologists with one certification, a growing number of trainees are doing multiple fellowships.

These numerous options can leave residents a little lost and confused. Are we taking the right steps to achieve a career that is both professionally and personally satisfying? Faced with ever-expanding medical knowledge in every subspecialty and the advent of personalized medical treatment, can we ever know enough to be effective “generalists”? Or, will we limit our future career opportunities if we focus on a single subspecialty?

## Advice from Practicing Pathologists

Members of the ASCP Resident Council have many of these same questions and concerns. We have tried to develop some resources to help residents figure out what career path is best for them. Advice on how to do this and areas where ASCP resources might be helpful follows:

- Begin by identifying your own personal goals and objectives. Do you have or plan to have a family? Where do you see yourself living and practicing? What do you value more—increased pay or extra time off? Prioritize your personal preferences and discuss them with your family and others in your life. Decide which items are open to compromise and which are not.
- Find a mentor or role model—someone with professional and personal goals similar to your own. One person may not fulfill all your mentoring needs. In that case, have more than one. You will simply have to blend together what you learn from each person. Ask your mentor and other practicing pathologists how they found the opportunities that led them down their various career paths. Make sure you find out what worked and what did not.
- Look for networking opportunities that can help you identify potential mentors from other institutions, if your program doesn't have a faculty or staff member that meets all your mentoring needs. For example, attend or volunteer to work at the upcoming ASCP Annual Meeting and other continuing education programs. The ASCP Resident Council Subspecialty grants also can be a great way to gain exposure to practicing pathologists at another institution, as well as work within an advanced field not available at your residency program.

## More Positive Advice

- Don't burn bridges. Pathology is a relatively small and specialized field. You never know when you might have to work with a former colleague—whether it is an attending physician or a blood bank

technologist—at another facility. You can never have too many friends or allies. Again, a good way to get and stay connected is by attending annual meetings and other ASCP programs and by participating in the subspecialty grant program.

- Get all of the certifications you can, even if it means re-taking the primary certification exam or paying the extra money to take a subspecialty certification exam you are qualified for, but may not use in your next job. You can never be too qualified. Also, get acquainted with ASCP's "re.member.moc" program, which gives members access to an online solution to better manage Maintenance of Certification (MOC) requirements from the American Board of Pathology.
- Make the journey as enjoyable as the destination. Although we all have to go through difficult stretches in our training, it should not be your overriding theme. When things start to get overwhelming; stop, look around, and focus on what is really important. Put aside some of the less imperative things on your "to-do" list and make time for personal items, such as taking your significant other out for dinner or going on a vacation. Even a couple days off can make your work more productive and fulfilling.
- Always try to look at the bigger picture. When we do things that stretch our capabilities and take us beyond our regular training program—whether it involves teaching medical students or participating in ASCP advocacy efforts—we are giving back in ways that help the future. But these activities also contribute to our own knowledge and capabilities, and, one day, they may pay unexpected dividends.

I welcome your feedback. If you have any questions, comments or suggestions, please e-mail them to me at [ResidentCouncil@ascp.org](mailto:ResidentCouncil@ascp.org).

*Dr. Kozel is Resident Physician at University of Missouri Healthcare, Columbia, MO.*







# The New Environment of Clinical Governance

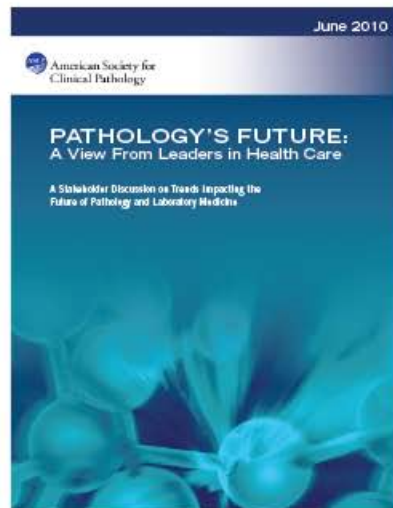
*An excerpt from Pathology's Future: A View from Leaders in Health Care, published June 2010 by the American Society for Clinical Pathology. The full report is available at [www.ascp.org/pathologysfuture](http://www.ascp.org/pathologysfuture).*

In the 10 years since the Institute of Medicine (IOM) report, *To Err Is Human*,<sup>1</sup> the healthcare industry's emphasis on improving patient safety has exploded. From the steady rise of hospital-acquired infections to infants receiving blood thinner overdoses at two major hospitals, a variety of trends and events have thrust the issue into the public spotlight.

Despite advances in patient safety procedures and the proliferation of safety literature touting the importance of everything from public reporting to hand hygiene, quality remains inconsistent. As safety issues not only endanger patients but also threaten providers' bottom lines through longer lengths of stay and higher costs, senior leaders have plenty of motivation to keep patient safety at the top of their priority lists. Improving patient safety continues to be one of the most urgent issues facing health care today.

The laboratory, with its long history of quality control and quality management, has been a pioneer in the development and implementation of processes that ensure accuracy and precision. It was the laboratory that introduced such concepts as "quality control," "quality assurance," and "quality management" to patient care processes. However, traditional tools for assessing laboratory efficiency have been limited to internal indicators, such as turnaround time, internal quality assessment, productivity, and cost. The new environment of "clinical governance" calls for a focus on effectiveness and outcome as well as efficiency.

As in other areas of patient care, there is increasing interest in evaluating the impact of laboratory testing on clinical and economic outcomes. This interest is being driven by the evolving healthcare system, the pressure to reduce laboratory costs, changes in reimbursement for laboratory tests, the need to demonstrate efficiency and efficacy, new regulatory requirements, and the increasing relevance of appropriateness and patient safety issues. Outcome measurement must include a quantitative assessment of



the benefit of medical and clinical interventions whose final impact on quality of life is probably the most reliable way of assessing outcomes.

An emerging and much broader approach to health assessment looks beyond care to the economic and social conditions in which people live that determine their health. Virtually all major diseases are primarily determined by a network of interacting exposures that either increase or decrease an individual's risk for disease. This is particularly true of cardiovascular disease and Type II diabetes. As stated in *Social Determinants of Health: The*

*Solid Facts* (WHO, 2003),<sup>2</sup> "While medical care can prolong survival and improve prognosis after some serious diseases, more important for the health of the population as a whole are the social and economic conditions that make people ill and in need of medical care in the first place. Nevertheless, universal access to medical care is clearly one of the social determinants of health."

As the fields of pathology and laboratory medicine look to establish a new paradigm of practice, diagnosing, and treating existing disease remains a high priority, but not to the exclusion of taking action on the underlying social determinants of health.

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Hilborne



Chiou

## Important to **MEDICINE** and Important to **LABORATORY MEDICINE**

By Lee H. Hilborne, MD, MPH, FASCP, DLM(ASCP)<sup>CM</sup>,  
and Paul Chiou, CT(ASCP)





- What should be included in a basic benefit plan that should be specified as part of a healthcare reform package?
- Should patients be required to visit a primary care physician before seeing a surgeon?
- Do coagulation clinics with associated laboratory testing produce better patient outcomes than using routine infrastructure for coagulation testing?
- Should patients have to make a 20 percent copayment for laboratory tests? What would happen if that copayment was only 10 percent? Could payers, including the federal government, control excess utilization without decreasing quality if they instituted such a requirement?

- Which laboratory services, when offered to a healthy patient during a routine physical examination, reduce morbidity and mortality from disease? For a given clinical situation, for which laboratory tests do the benefits exceed the risks by a sufficient margin that they are worth doing?

- Do trained and certified medical laboratory scientists produce higher quality laboratory results than individuals with lesser training?

You cannot make the right decisions to these very important questions based on the results from

an autoanalyzer or by screening a glass slide. The answers to these questions come from a very different scientific discipline known as Health Services Research (HSR).

Unlike the basic sciences that study what happens on a microscopic, chemical, or molecular level, HSR is a multidisciplinary approach to answering policy and social questions that looks at how the healthcare system affects people's health outcomes. It specifically focuses on access to care, quality of care, cost of care, and the impacts of health technologies. It seeks to provide answers that will lead to health improvements in the general population<sup>1</sup>. The basic components of a health services research include surveys, cohort studies, case control studies, and randomized controlled trials.

HSR is important to laboratory professionals because the data that are generated inform us about the quality and effectiveness of new medical devices, assays, and approaches as they relate to patient care and cost-effectiveness. Findings from HSR can also shed light on laboratory practices and procedures, leading to new and more effective ways of executing and streamlining laboratory tests.

Let's explore a few more laboratory medicine examples that highlight the importance of HSR studies.

ASCP's Wage and Vacancy Surveys fall into the spectrum of health services research. The vacancy survey information informs us about the status of our professional workforce, including the current and future regional needs of laboratory personnel. It also offers recommendations for policymakers on how best to respond to workforce challenges. It serves as the basis for discussing the spectrum of public and private options to change policy and guide decisions to ensure that the future laboratory workforce is as strong, or stronger, than in years past.

Earlier we asked the question whether testing, when performed by trained and certified medical laboratory scientists, yields more dependable results than when testing is performed by less experienced individuals. This has been a bit of an elusive question. However, in 1998 both the Centers for Disease Control and Prevention (CDC)<sup>2</sup> and the California Department of Health Services<sup>3</sup> published

studies that demonstrated that repeat proficiency testing failure was more common in laboratories (e.g., physician office laboratories) that did not use certified personnel when compared, on the same tests, to laboratories that



use certified personnel (essentially those certified by the ASCP Board of Certification). The California study went one step further when researchers there looked at differences in proficiency testing between clinical laboratories (e.g., hospital and reference laboratories) and physician office laboratories (POLs). Although clinical laboratories clearly performed better than POLs, consistent with the national findings from CDC, POLs that employed medical laboratory scientists performed better than those POLs that used untrained personnel.

Although these two studies and a few others have shown the correlation between trained personnel and proficiency testing performance, many still contend that this is a controlled setting and what we really need to know is whether patients have better outcomes when their laboratory tests are performed by trained and certified personnel. These follow on studies have been particularly difficult

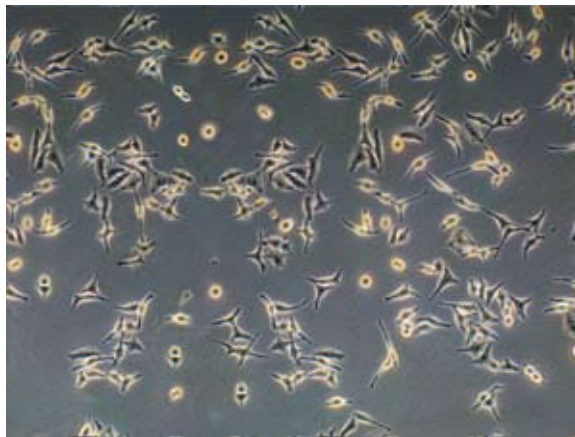
to define—in part because most laboratory test results are inputs to subsequent processes of care and patient outcomes may be influenced more by those subsequent processes than whether the test result was exactly on target. However, CDC is funding a number of research studies that expect to shed further light on this subject.

Beyond the concerns for testing accuracy, those who pay for healthcare services, including laboratory services, are examining whether in-office ancillary services, such as laboratory testing, creates what are known as *perverse incentives* that drive the overuse of those ancillary services. Although in-office laboratory testing does in fact constitute a form of self-referral, this service is exempted under federal law from the usual rules of self-referral under the assumption that near patient testing improves the speed of diagnosis and the overall quality of patient care. Applying the principles of health services research, a recent report demonstrated that for five common tests (CBC, electrolytes, hemoglobin A1c, cholesterol, and prostate specific antigen) were performed more frequently by specialist physicians when they had a laboratory in their office than when the physician's office did *not* have an in-office laboratory<sup>4</sup>. Test ordering practice differences were not observed among primary care physicians with and without in-office laboratories. The researchers used the ambulatory care database collected by the National Center for Health Statistics, a branch of CDC. Although it is not entirely clear whether specialists with laboratories overuse services or those without laboratories actually order too few tests, the authors conclude that underuse is less likely given the lack of association for primary care physicians. If there really is overuse, the findings suggest potentially hundreds

of millions of dollars may be unnecessarily spent each year on unneeded tests. Based on these types of findings, those planning for healthcare's future may wish to consider checks and balances to ensure that tests ordered are in fact medically justified.

Are pathologists, and their findings, important for patient outcomes? How important are clinical practice guidelines in ensuring patients get the maximum benefit from the healthcare services they receive? Should payers

provide incentives for physicians to use clinical practice guidelines? These questions have been the subject of discussions for the last several decades. With the promulgation of healthcare reform there is increased interest in answering these questions. Most clinical practice guidelines focus on process of care (i.e., what we actually do) while what matters most to people is whether the outcomes of care (what really happens) are optimal. HSR studies are now beginning to show links between process



HeLa (cervical cancer) cells in culture.

and outcome. For example, one study demonstrated that when treating patients with breast cancer, when clinical practice guidelines were completely followed (including the pathologist's component), survival was better than when there was less complete compliance<sup>5</sup>. It is likely as we continue to get better data through HSR, studies will add to the body of evidence that demonstrates both the value of pathologists and other laboratory professionals. These findings will be invaluable in ensuring adequate funding for laboratory medicine services and for advocating for the expansion of training programs for laboratory professionals.

## HSR in Cytology

Cytology, like much of laboratory medicine, has experienced substantial changes since the time when the technique was first described by Dr. Papanicolaou, including the way slides are prepared for review to the instruments that work with our cytotechnologists and cytopathologists to evaluate cells. A significant debate emerged in the field of cervical cancer screening over the past two decades concerning whether the newly FDA-approved, mono-layer slide preparation technology was better than the traditional conventional slide preparation. To answer this question, many studies were undertaken, including clinical trials in which researchers randomly assigned patients and their specimens to one of two slide preparation methods. Then they reviewed data, including the sensitivity, specificity, unsatisfactory rates, transformation zone detection rates, and microorganism pick-up rates of each approach. Policymakers, as well as lab managers, carefully evaluated the findings of these HSR studies to assist them in shaping their perspectives on this new liquid-based cytology.



More important, these data were used not only to encourage adoption of mono-layer technology. The findings were also used to approach those involved in payment policy to ensure that the use of new collection and screening systems were reimbursed by both public and private insurers.

Today, with two mono-layer systems approved by the FDA in 2003 and 2008 respectively, decision makers are asking which of the three screening approaches, including the manual conventional method, is the most effective for detecting cervical cancer<sup>6</sup>. If one considers cost, with the liquid-based methods being priced higher than conventional cytology, does the risk/benefit equation change<sup>7</sup>? As a screening test, cervical cytology must have a high degree of sensitivity with an acceptable degree of specificity. Once again, they must turn to HSR to help answer their questions and shape their perspectives.

The future of our profession very much depends on data that have been and will be generated through health services research. Our profession needs more members who are trained in HSR techniques. As one of the most data-driven disciplines in healthcare, our profession is probably better positioned than any other to harness the information that exists in our laboratories and in our healthcare systems.

*Dr. Hilborne is Medical Director, Quest Diagnostics, Southern California, West Hills, CA. Mr. Chiou is a cytotechnologist with Pathology, Inc., Torrance, CA, and is pursuing a master of public health at University of Massachusetts, Amherst.*

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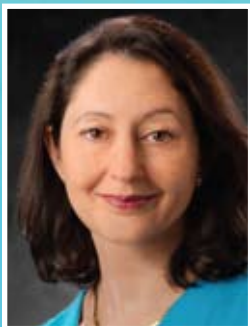
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Snyder

# Laboratory Medicine Quality Improvement: **A Research Practitioner's View**

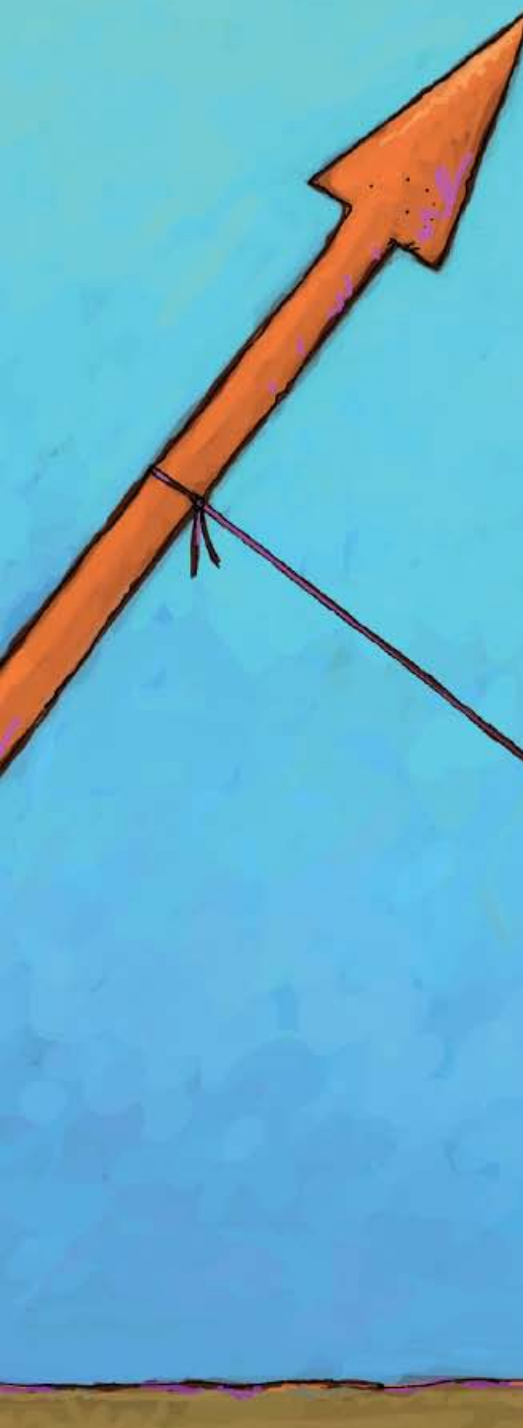
By Susan R. Snyder, PhD, MBA

Illustration: Tom Payne





# E V I D E N C E



An overarching goal of the evidence-based movement in health services research is to improve healthcare decision making and accountability related to health outcomes and resource allocation. While there are many terms used, the basic objectives are to generate, synthesize, and use evidence to address three basic questions<sup>1</sup> related to healthcare services:

- 1) Efficacy: Can it work?
- 2) Effectiveness: Does it work?
- 3) Economic Value: Is it worth it?

Of these, the most important for health services research is No. 2. While primary clinical research addresses the first question, efficacy doesn't generally translate into effectiveness or real-world health outcomes, and is not focused on quality improvement. To answer No. 3 (aka "the business case"), a necessary condition is to first answer "yes" to No. 2. For quality improvement research to be successful for improving outcomes, it must determine what works *in practice*. This requires having an adequate evidence base comprised of relevant data or studies conducted in routine practice settings. Observation or opinions alone do not constitute evidence of effectiveness or value.

More than in other areas of health care, health services researchers working in laboratory medicine find that making progress in outcomes-oriented research requires a paradigm shift. It begins with recognizing the difference between commonly accepted practice and guidance that is not evidence-based (e.g., consensus-based standards) versus some evidence-based support. When the latter applies, it is essential to recognize the need to evaluate the adequacy of the evidence because not all evidence is equally valid or substantive.

The good news is that many laboratory professionals, by nature and from their training and work, already possess the basic requirement of this paradigm shift: scientific perspective. Evidence-based laboratory medicine (EBLM)<sup>2</sup> requires that scientific perspective be applied in unfamiliar ways: questioning accepted conventional wisdom about laboratory practice, including from authoritative sources, respected educational and training materials, and their own professional organizations. This may routinely require thinking and acting from a perspective outside the status quo comfort zone to collectively move further down the learning curve for the concepts of evidence-based laboratory practice. Progress toward the foundations of evidence may be subject to not only overcoming the usual evidence-related challenges (such as meaningful definitions of outcomes-related objectives) but also political challenges as well that require going beyond the status quo and expert opinions. Whatever the reasons holding up progress, allowing evidence-based research to flourish puts all of laboratory medicine on the road to achieving a shared objective—demonstrating the value of laboratory medicine to clinicians, policy decision makers, and third-party payers.

When available evidence for an important healthcare quality issue is limited or nonexistent in medicine, the status quo has been to address the problem with some form of expert opinion, consensus standards, or practice guidelines. Under an evidence-based paradigm shift, this situation would be viewed as a problem that needs to be addressed by having well-defined outcomes and data. What these divergent views highlight is a positive opportunity for developers of standards and guidelines as well as professionals dedicated to employing a more rigorous approach to healthcare quality improvement, to collaborate with evidence-based health services researchers on priority issues that require evidence to validate the practice as a standard of care. (Warning: Variations in care without evidence are red flags that should draw universal concern of unnecessary, ineffective practices.)

A common goal of guidelines is that the “standard of care” should optimize healthcare quality and patient care. Making the “standard of care” evidence-based simply translates into a requirement that patient-related outcomes should be measured to demonstrate whether patient benefit and/or quality improvement is likely. This is the purpose of two evidence-based laboratory medicine quality improvement initiatives at the Centers for Disease Control and Prevention (CDC) (laboratory medicine best practices and EBLM performance measures) that rely on an evidence-based approach known as *systematic review*. The focus of these initiatives is on laboratory medicine’s interface between clinicians and patients, the pre- and post-analytical testing phases of laboratory testing where there is the greatest opportunity for improvement and impact on healthcare quality.<sup>3</sup> Quality is determined by outcome measures consistent with the Institute of Medicine’s healthcare quality aims (safe, timely, effective, efficient, equitable, and patient-centered).<sup>4</sup>

In general, the greatest challenges in evidence-based research relate to the limited quality and quantity of available evidence. Available published studies commonly lack key elements that comprise good research study conduct and

reporting, as well as standardized definitions and measurement methods for outcomes. In laboratory medicine these challenges are compounded by the fact that (laboratory) testing’s direct outcomes are one step removed from the health-related and patient outcomes that are of greatest interest. Laboratory test results provide information that may affect a clinical decision (diagnosis, treatment, management) that may then impact patient health.<sup>5</sup>

Systematic reviews are like scientific investigations in themselves, using pre-planned, organized methods to assemble all the original primary studies (data) that meet their criteria to address a particular issue or research question, with subsequent critical assessment and synthesis of the results using strategies and methods that limit bias and random error. A quantitative systematic review often summarizes results using a statistical technique called meta-analysis when studies are comparable, to estimate a summary effect size and confidence interval. This technique allows researchers to combine or pool the results of several studies into a single combined estimate. Systematic review methods emerged in the 1980s and have proliferated, creating a systematic review/research synthesis science. Systematic reviews are included in the definition of “comparative effectiveness research,” recently re-branded as “patient-centered research.” Whatever name is used, the goal is the same—to evaluate effectiveness (what works) using outcomes data.



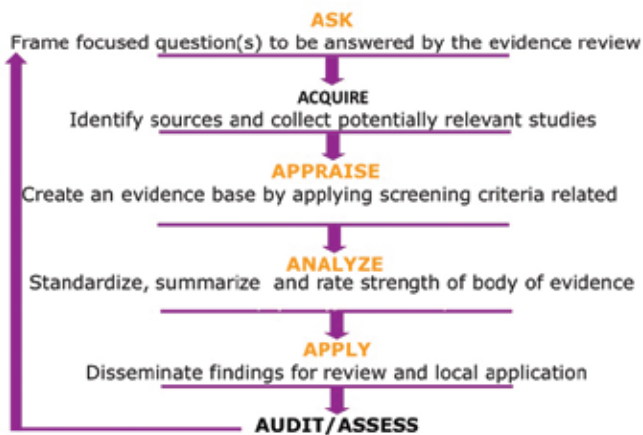
The CDC Laboratory Medicine Best Practices (LMBP) initiative has been working to make the evidence-based paradigm shift using systematic review methods. (See “Laboratory Medicine Best Practices Initial Progress Report,” *Critical Values*, January 2010.) This work is supported by a contract with Battelle Memorial Institute. Initially, the LMBP Workgroup and staff<sup>6</sup> found that making progress required addressing what had been three too-big-to-solve problems: 1) lack of evidence (quantity and quality), 2) lack of standardized measures for improving healthcare quality, and 3) methods for including nonrandomized study designs as evidence. The LMBP applied traditional systematic review methods in its 2006-2007 proof of concept, which produced multiple findings verifying there was very little accessible evidence that met standard systematic review inclusion criteria. The conclusion was that this type of EBLM quality improvement research required developing new solutions to bridge these gaps.

The key directive of the LMBP Workgroup was to work efficiently by using existing methods and not reinvent the wheel. While being very open and inclusive of all potential approaches, few models were found to build on, and none addressed use of quality improvement evidence. Despite good intentions for EBLM progress and the added motivation for laboratory medicine to be recognized with a seat at the table in the major national health reform policy discussions, there had been no concerted effort to substantively address and solve any one of these problems.



The first priority for the LMBP initiative for making evidence-based “best practice” recommendations was to develop transparent and scientifically sound methods to allow inclusion of quality improvement studies, typically nonrandomized, observational study designs, as evidence of practice effectiveness. The newly developed methods have been named the LMBP A-6 Cycle,<sup>7</sup> adapted from other tested systematic review methods (e.g., Guide to Community Preventive Services,<sup>8</sup> GRADE,<sup>9</sup> Cochrane Collaboration,<sup>10</sup> U.S. Preventive Services Task Force,<sup>11</sup> AHRQ Effective Healthcare Program<sup>12</sup>).

## LMBP Systematic Review “A6” Steps



The LMBP methods generally conform to systematic review and meta-analysis principles, with a major differentiating principle addressing the needs of quality improvement systematic review research. Specifically, it is preferable to evaluate meaningful quantitative outcomes from observational studies that are standardized, reproducible, and independently verifiable using generally accepted good practices for nonrandomized research rather than exclude it from evidence or not have evidence, or both.<sup>13</sup>

Solving the systematic review methods problem through the novel LMBP A-6 Cycle and then adopting an “if-we-build-it-they-will-come” optimism regarding available evidence was clearly not warranted from experience. There was still not enough published evidence of practice effectiveness available for laboratory medicine quality improvement systematic reviews. Moving this EBLM initiative forward required additional innovations for accessing more evidence. To achieve this, the LMBP initiative created an approach and corresponding methods to increase the limited quantity and quality of available evidence—the primary challenge in evidence-based research.

The LMBP team developed a means for obtaining and generating new, unpublished evidence that could be included in systematic reviews. It relies on Web-based and electronic approaches for soliciting, collecting, and reviewing

unpublished practice evidence. The same review methods and evaluation criteria are applied to both the unpublished and published studies. To make this actually work in practice requires collaboration with potential sources of unpublished evidence, so the LMBP initiated development of a network of laboratory and healthcare organizations and professionals, including the ASCP. This partnership with laboratory medicine stakeholders sharing a common interest in evidence-based research facilitates both contributions of quality improvement data and information that can serve as evidence, as well as the dissemination and application of LMBP evidence-based practice findings and recommendations.

The research, development, and pilot testing from 2007 to 2009 of the new LMBP quality improvement systematic review methods, along with the network and a Web-based data submission process for unpublished studies, culminated in the following 2010 accomplishments:

- Establishing the LMBP A-6 systematic review methods;
- Completing seven practice evidence reviews covering three quality improvement topic areas (patient specimen identification, critical values test result communication, and blood culture contamination);
- Creating the LMBP Network of partners; and
- Re-launching a new and improved LMBP Web site: [www.futurelabmedicine.org](http://www.futurelabmedicine.org).

A peer-reviewed journal publication of the LMBP methods and evidence reviews are anticipated later this year, and information will also be available on the LMBP Web site. Visitors to the LMBP Web site will find more information on work-in-progress, may register to receive updates and more information, can provide input on new potential evidence review topics and practices, offer feedback on methods, and submit data/studies for active evidence review topics.

## Quality/Performance Measure Evaluation

The second CDC EBLM initiative is Evidence-Based Laboratory Medicine Quality/Performance Measure Evaluation.<sup>14</sup> It addresses the need for laboratory test-related measures focused on important healthcare quality gaps consistent with national health priorities.<sup>15</sup> The purpose is to produce outcome measures for reporting performance that also serve as quality improvement tools for evaluating and encouraging evidence-based practice in the pre- and post-analytical testing phases. While there is rarely direct evidence measuring the effect of laboratory testing on patient-related outcomes, a chain of evidence linking tests and quality improvement practices to these outcomes can be developed. Effectively completing the chain of evidence involves framing, connecting, and then answering mul-

multiple systematic review research questions, often with very limited evidence.

To support this work, CDC funded three cooperative agreements from 2007 to 2010 and additional new awards in 2010. Previous awardees are Kaiser Permanente Center for Health Research for chronic kidney disease, Texas State Department of Health Services for newborn screening, and the University of Colorado Denver Department of Pathology for clinical and anatomic pathology patient safety issues. Progress for all three has been fraught with challenges due to lack of relevant data. Nonetheless, the investigators and their teams have creatively used both conventional and novel methods to develop needed evidence-based results, including original data collection. These efforts demonstrate that success in quality improvement, evidence-based research may routinely require thinking outside the box and employing innovative strategies. All three awardees plan to publish the results and associated outcome measures. This exemplifies the type of health services research necessary for laboratory medicine contributions to be valued and recognized consistent with having a standing invitation for that much lamented 'seat at the table' for national healthcare policy.

## Future Success Requires Grass Roots Participation

To a large extent the future success of these CDC EBLM initiatives and the EBLM paradigm shift in quality improvement depends on substantive grass roots laboratory medicine participation to effectively increase data and analysis related to healthcare quality outcomes. The CDC's investment in research and development for the two EBLM initiatives has paid off by providing tangible means and methods for addressing the barriers to evidence-based quality improvement in laboratory medicine. The initial results of this work demonstrate real progress that can be joined by others to successfully collaborate and more broadly implement an EBLM paradigm. For those involved in EBLM efforts, progress involves a commitment to new approaches to difficult problems that have not been previously attempted. Solutions routinely require new ideas and inventing new methods to collect data. EBLM progress and its impact will depend less on supply than on demand from laboratory professionals. Generating demand not only requires support from influential organizations and leaders, but on broad-based engagement and participation from the entire field to change laboratory medicine norms and expectations. The key to change and success of these pioneering health services research initiatives is simply "just do it," because the alternative of not getting it done may prove detrimental not only to laboratory medicine's future but to the nation's health.

*Dr. Snyder is Senior Economist and Evidence-Based Laboratory Medicine Project Lead, Office of Surveillance, Epidemiology and Laboratory Services (proposed), Centers for Disease Control and Prevention, Atlanta, GA.*

**Disclaimer:** The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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# Experienced Haitian-American Pathologist Brings Objective Eye to Scene of Destruction

By Marise B. McNeeley



McNeeley

**A**SCP sent a delegation of volunteers to Haiti in June 2010 on a three-week mission to improve laboratory services that were disrupted by the earthquake that devastated the already poverty-stricken nation in January. I was among the delegation that also included Rosemary Edwards, MD, FASCP; Marie N. Fidelia-Lambert, MD, FASCP; Von Samedi, MD, FASCP; and medical technologist Daniel Yavo.

Our job was to evaluate the needs and make recommendations to improve laboratory operations and quality assurance at two public hospital-based clinical laboratories: Hopital de l'Universited'Etatd'Haiti (HUEH) and HopitalUniversitaire de la Paix (HUP).

I was born in Haiti and spent more than 10 years directing the laboratory of Holy Cross Hospital in Leogane, which was at the epicenter of the earthquake. As a result, I was familiar with the infrastructure and administrative issues of laboratory operations in Haiti.

Only a handful of clinical laboratories benefit from physician oversight. Among them are The National Laboratory of Public Health directed by Jacques Boncy, MD, and HUEH directed by Elsie Michel-Salnave, MD. Physicians are not attracted to clinical pathology because most laboratories are run by laboratory technicians. Limited

government oversight of clinical laboratories, including regulations requiring minimal personnel standards, impedes progress toward improved quality laboratory services.

Anatomic pathology is better accepted in the Haitian medical community. However, only 10 pathologists provide anatomic pathology services for the entire country. The majority of patients pay out-of-pocket for their healthcare. The price of a complete blood count at HUP is 25 gourdes (less than \$1)—prohibitive for many families that have little or no income.

Before the earthquake, infrastructure—including transportation, clean water, electricity, sanitation, housing, and healthcare—was tenuous at best. Not surprisingly, the earthquake created extraordinary conditions. The streets of Port-au-Prince are packed with people and traffic throughout the day due to damaged roads, obstructions caused by collapsed buildings, and homeless people living in temporary tents placed on streets and sidewalks.

On the ASCP mission, I focused on the interpretation of peripheral blood smears. I discovered quality issues attributable to, among other things, re-use of glass slides, weak staining intensity, substitution of mineral oil for immersion oil, and the use of optically challenged microscopes.



## SPECIAL REPORT



My greatest surprise and satisfaction while visiting Haiti was that in spite of the devastation and loss, the laboratory professionals were not full of despair. Many attribute their positive attitude to our visit and the hope that we would continue to help them improve the medical care they can provide.

*Dr. McNeeley is Associate Director of Anatomic Pathology for Clinical Trials at Quest Diagnostics, Teterboro, NJ.*

# ASCP Mission to Haiti



**M**arie N. Fidélia-Lambert, MD, FASCP, grew up in Port-au-Prince Haiti. The oldest of three siblings, Dr. Fidélia-Lambert earned her medical degree from the State University of Haiti. She then moved to the United States, where her mother had immigrated in the mid-1960s. She joined the U.S. Army as a Medical Laboratory Specialist and later the Pathology Residency Training program at Howard University Hospital in Washington, DC, where she currently practices.

But she never forgot the poverty in Haiti. Following the earthquake in January 2010, she was one of hundreds of Haitian-American medical professionals who returned to Haiti to help. An outgoing, warm woman with glasses and a big smile, Dr. Fidélia-Lambert made two visits after the quake—first helping a clinic near her parent's hometown in southeastern Haiti and then joining a team of five volunteers in June as part of the American Society for Clinical Pathology's effort to improve the functioning of the laboratories in Haiti.

Going back to Haiti was an emotional experience for her. "I remember my reaction seeing it on TV—the collapsed buildings, the tents, the crowds everywhere, but the most shocking thing was the number of deaths and the piles of bodies," she said as tears formed in her eyes. "This was the most horrific thing for me. It was unbelievable. Just too much."

## Conducting far-ranging assessment

At the Hospital of Peace (Hôpital Universitaire de la Paix), Dr. Fidélia-Lambert took part in an assessment of the laboratory, and developed policies and procedures, educational trainings, and follow-up templates designed to improve the workflow and patients' care. The laboratory personnel and the hospital administration, she said, were very receptive to ASCP's help.

"When we first understood the challenges after our assessment, we called this 'Mission Impossible,'" Dr. Fidélia-Lambert said. "But as we go on and actually start getting things done, we're learning that it's easier—that it's possible."

The dire healthcare situation in Haiti, accentuated by the devastating earthquake of last January, makes her want to hasten her dream of going back to Haiti. She is planning to move back to the Jacmel region (home to both of her parents) in southeastern Haiti.

"I feel I can help more in Haiti than in the States," she said. "What I am seeing in Haiti is that a lot can be done with a little. Where there is a will, there is a way."

# 'Mission Impossible' T







Marie N. Fidélia-Lambert, MD, FASCP

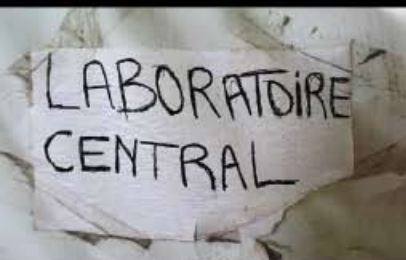
# Tackled Task by Task







Daniel Yavo



Von Samedi, MD, FASCP

## Desire to Help Arose from Memories of Civil War

Daniel Yavo knows what it's like to have the ground fall away beneath his feet. Although it was civil unrest and not an earthquake that destroyed the tranquility of his village in Côte d'Ivoire eight years ago, he understood the despair of the people of Haiti, and he knew he wanted to help.

"I really needed to do something concrete," said Yavo, a medical technologist and Quality Assurance Coordinator Assistant with the Centers for Disease Control and Prevention in Atlanta. "I had the option to come myself and contribute my time and see how we could advise them. I was happy to do something."

He responded quickly to an invitation from ASCP to join a team of consultants traveling to Haiti in June. "I told them it would be good to help this country that has been devastated by the earthquake," Yavo said. "I had seen people suffer in my country's civil war, and I saw how the people of Haiti were suffering with this earthquake."

On a rainy Thursday in June, Yavo was in Port-au-Prince, working in a makeshift laboratory in Haiti's State University Hospital (Hôpital de L'Université d'Etat d'Haiti), whose roof is the taut canvas surface of a tent. The previous laboratory inside the hospital had been destroyed in the Jan. 12 earthquake.

"It is so sad to see," Yavo said. "This is a very small space, and more than 30 of us must work here and in very hot conditions; the equipment is faulty, and we can't really ensure the safety of the biological substances. Mornings, some 200

patients line up to be seen for hours. They travel here from all over Haiti, but we can only see about half of them. Sometimes they must return three and four times to get their lab results."

Yavo's volunteer mission was divided in two phases: He assessed and evaluated the needs of the facility and its workers, and then presented short-, medium-, and long-term plans to the laboratory manager and director for ensuring the safety of the laboratory and improving the efficiency of the workflow ultimately to produce better diagnostic results.

"Ultimately what we want is for the patients to be served better by the laboratory," Yavo said. It is a yearning for normalcy that is familiar to him.

When civil war exploded in Côte d'Ivoire in 2002, Yavo's home village of Bouaké became the epicenter of the rebellion. His family lost everything—their house and land, but his parents remained. When the fighting became very bad, he begged them to join him and his wife and three children in Abidjan.

In the end, his mother and father gave in to his pleas. They endured a journey of 205 kilometers through the war zone to reach his car and travel to safety. His modest home in the city became a refuge for family members; more than 20 of them lived with him for months.

"My grandmother stayed behind," Yavo said. "She was too sick to travel. And there was no one to take care of her. I did not see where she was buried."

## Pathologist Returns to Childhood Home to Help His Country Heal

After the devastating earthquake in Haiti in January, Von Samedi, MD, FASCP, a pathologist at Beth Israel Deaconess Medical Center in Boston, watched televised news reports with his wife around the clock. He couldn't sleep at night. He wanted to be in their homeland.

"The day after it happened, my wife and I put our name on all of the lists," he said. "We know Creole and French, and we wanted to help. But no one could use pathologists."

Months later, he got his chance. ASCP sent an announcement looking for volunteers, and in June he was among a volunteer corps of four pathologists and one medical technologist working to improve laboratories in Haiti's State University Hospital (Hôpital de L'Université d'Etat d'Haiti) and Hospital of Peace (Hôpital Universitaire de la Paix).

The state university hospital had been destroyed and was re-established under tents. He co-wrote a detailed report assessing the laboratory and recommending key improvements that—even in the post-quake Haiti environment—could be implemented.

Dr. Samedi grew up in a middle-class family in Port-au-Prince until age 18, when he went to college in Boston. When he returned in June, his old world looked dramatically different, and he grappled in dealing with all the destruction before him. Even his old school, once well-tended, was gone—its grounds taken over by hundreds of squatter tents.

"The shocking thing I see now is all of the misery and how people still function," he said. "People move on. But I see misery in their faces. There are thousands of kids on the street. The bulk of the damage went to the poor areas."

Dr. Samedi's commitment to his home country was clear in the work he did in the laboratory, where he and his fellow volunteers emphasized the need for more patient-centered healthcare.

The ASCP assessment noted that patients had to shepherd their own clinical order from the clinician to the laboratory, wait in lines to register their tests, and obtain the supplies for having their samples taken. Patients then had to leave to deposit their samples or have their blood drawn on site, and then return and wait in another line to obtain their results.

The tent lab saw a daily bottleneck of typically 200 patients jammed together, waiting. "The patient should be the most important person in the process," said Dr. Samedi. "The healthcare system should not be putting it all back on the patients."

Through ASCP's mission, Dr. Samedi was uniquely positioned—as a pathologist and a Haitian—to deliver this message to his compatriots.





Rosemary Edwards, MD, MPH, FASCP



Von Samedi, MD, FASCP, Marie Lehner, ASCP Global Outreach





# New Experience for Veteran Consultant to Haiti

Rosemary Edwards, MD, MPH, FASCP, a pathologist at Butler Memorial Hospital just north of Pittsburgh, has traveled to Haiti more than 20 times in the past 10 years, but the ASCP mission to Haiti was different.

“While I’ve had much exposure to small clinic level labs, this was my first in-depth experience in a hospital lab,” she said. “Also, working as a member of an international team alongside Haitian-American pathologists and Daniel Yavo from the Cote d’Ivoire was great.”

As a volunteer for the ASCP-funded relief effort in June, she spent one week consulting with laboratory personnel in Haiti’s Hospital of Peace (Hôpital Universitaire de la Paix). It was her second visit to Haiti this year.

Her work involved producing procedural documents—an organizational chart, job descriptions, and orientation forms—for the laboratory. They were needed to improve efficiency with limited resources. She also helped the laboratory with inventory control. She cited several instances in which the laboratory lacked the supplies to perform a complete blood count.

“When we investigated further, we found that this seemed to be an inventory issue,” said Dr. Edwards. “They had written down the total number of tests but not the specific kinds of tests, so there was no basis for establishing an inventory system.”

“We suggested that they write out a daily and weekly log on the types of tests they are performing,” she continued. “You need to order supplies far enough in advance, so you don’t run out, but not too many, since reagents expire and storage is tight.”

They discovered as well that the laboratory was reusing glass slides and using glycerin instead of microscope oil to examine hematology smears.

“They were neither clean nor dry, and they had traces of soap scum, fibers of toilet paper, and fingerprints,” she said. “We suggested they only reuse slides for stool samples and avoid their use for hematology.”

In February, not long after the earthquake, Dr. Edwards worked in a clinic where she had served as executive director.

“After the earthquake, the buildings where we lived and worked were gone, our employees lost family members and their homes,” she said. “Yet the staff continued to show up each day to help each other and to help members of the community to get through this terrible tragedy.”

She was able to help some people, including an HIV-positive mother and her sick newborn baby, and a man who had been almost scalped by a falling piece of corrugated tin. “He was bleeding profusely,” Dr. Edwards said. “We hand-tied every single vessel in his scalp. He would have bled to death.”

Since the earthquake, she has met a number of pathologists and other lab professionals who are involved in lab development in Haiti and other developing countries.

“It makes me proud to be a member of our profession,” she said.

Dr. Edwards plans to return in the fall to help with rebuilding health programs. Her advice to those interested in volunteering is to keep in mind that you cannot “fix and change things by just telling people what is wrong. It’s part of an exchange, a sharing of ideas and practices.”

*Profiles by Ellen Wilson*

*Photos by Daniel McCabe*

More photos and an online story about the ASCP Mission to Haiti are available at [www.ascp.org/Haiti2010](http://www.ascp.org/Haiti2010). Want to join ASCP’s Global Outreach corps? Go to [www.ascp.org/OutreachApply](http://www.ascp.org/OutreachApply).

## Pathologists Must Serve Clinicians

It was interesting to read the opinions of Drs. Huppmann and Bollinger (“Establishing Our Image Through Brand Management,” *Critical Values*, July 2010) who are not yet practicing pathologists. Their cautionary comment about becoming doormats (“we need not always stop working when the clinical team drops by to see patient [sic] slides”) provoked me to write. They need to understand that pathologists must serve their clinicians. Patients are the source of all hospital revenue. Patients come to see clinicians, not pathologists. Clinicians, therefore, provide the source of all revenue. All pathologists-to-be must understand and accept this basic fact and its ramifications.

Gerson Paull, MD  
Atlanta, GA



Huppmann      Bollinger

### *Authors' response:*

We appreciate Dr. Paull reading our article. As practicing pathologists, we agree that patients should be the focus of our work regardless of one's position in the revenue stream. We also concur that customer service is imperative. However, many of us have encountered clinicians who exceed appropriate boundaries and lack professional courtesy. It is these cases to which we referred in our article.

We appreciate any interest and comments on the subject and hope that our article will stimulate further constructive discussion.

Alison R. Huppmann, MD, FASCP  
Bethesda, MD  
Thomas J. Bollinger, MD, MPH, FASCP  
Cedar Rapids, IA

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## Let's Broaden, Not Fragment, Pathologists' Impact on Patient Care



Tawfik

In the July 10 issue, oncologist Dr. Lynn Henry highlighted her vision of the complex and intertwining relationship between oncologists and pathologists (“Beyond H&E: How Should Pathologists and Oncologists Intersect in the Future?”). The challenges we face are many. There is a demand to improve and standardize our diagnoses and our communication skills. Some believe that our discipline is on the verge of extinction. To standardize and improve a test such as Her2 is definitely needed and should be demanded, but to paint a picture of blame and shortcomings for the pathologists is wrong. Similarly, to draw conclusions based on results obtained from the different molecular tests that we are bombarded with in such a short time is not wise. Logic and common sense teaches us that there are no

known tests to this day that could replace the valuable input of pathologists and their integrative ability.

One of the most significant results of the recent revolution in science and the medical field has been the creation of a vast body of knowledge, so fast as to be impossible to absorb. As a consequence, that led to fragmentation of that information into discrete communities of expertise that often reflect individuals' prior beliefs and preferences. In the pathology community, we should seek ways to use the new tools of technology to broaden, not fragment, our impact in health care. We should search for new ways to welcome those changes. We should attract the creative and progressive leader to face these new challenges, but we should never underestimate our value and contribution in patient care.

Ossama Tawfik, MD, PhD, FASCP  
Kansas City, KS



## Ball to Retire from ASCP in October

After serving eight years as ASCP's Executive Vice President (EVP), the top staff leadership position, John R. Ball, MD, JD, FASCP, retires at the end of October 2010. "John Ball is a giant in clinical medicine," said E. Blair Holladay, PhD, SCT(ASCP)<sup>CM</sup>, who assumed the EVP position July 1. "He established a significantly improved governance structure for ASCP and helped the organization bolster its finances. He did an incredible job forging alliances with clinical partners in medicine." Dr. Ball positioned ASCP as truly competitive in the field of pathology and laboratory medicine. "Moreover, John's an incredible communicator," said Dr. Holladay. "He cultivated relationships and in so doing set the stage for ASCP to be the go-to society for the future of pathology and laboratory medicine."



Ball

## ASCP, The Joint Commission Call for FDA to Assert Authority over High-Complexity Lab-Developed Tests

The time has come for the U.S. Food and Drug Administration to assert its regulatory authority over high-complexity, laboratory-developed tests, ASCP and The Joint Commission told the agency on July 20, 2010. ASCP President-Elect John E. Tomaszewski, MD, FASCP, testified on behalf of ASCP and The Joint Commission at a public meeting of the FDA Center for Devices and Radiological Health concerning the oversight of laboratory-developed tests. ASCP Board Member Kenneth Emancipator, MD, FASCP, also presented ASCP testimony on direct-to-consumer tests (DTCs). For full coverage, see [www.ascp.org/LDT](http://www.ascp.org/LDT).

## ASCP President Responds to New York Times Article on Errors in Breast Cancer Diagnosis

ASCP President Mark H. Stoler, MD, FASCP, issued a statement in response to a July 19 article in *The New York Times* about breast cancer misdiagnosis. Dr. Stoler wrote that the article "revealed a very real issue, but in our opinion has focused on only a small part of the problem. While it may be true that even well-trained individuals may occasionally make an interpretive error when reading biopsies, the bigger issue is that even for experts there are a variety of borderline or gray-zone lesions that diagnostically are not very reproducible." Read more at [www.ascp.org/2010NYT](http://www.ascp.org/2010NYT).

## 2010 Fellowship & Job Market Surveys

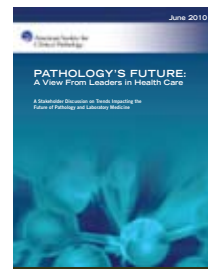
More than half of post-graduate year three and four pathology resident respondents to the ASCP Resident Council survey stated that they were interested in fellowships for the purpose of their long-term career interests. The remaining respondents indicated that fellowships were important to secure employment (35 percent) and because previously desired jobs were not available after their residencies (4 percent).



The annual Fellowship and Job Market Surveys track trends on fellowships and the overall job market for pathologists-in-training, including residents and fellows. The surveys are conducted as part of the Resident In-Service Exam (RISE), the Fellow Forensic In-Service Exam (FISE), the Fellow In-Service Hematopathology Exam (FISHE), and the Fellow Transfusion Medicine In-Service Exam (TMISE). A total of 2,791 individuals in various levels of training participated in the in-service exams. Read the entire report at [www.ascp.org/2010JobMarket](http://www.ascp.org/2010JobMarket).

## Pathology's Future: A View from Leaders in Health Care

In June ASCP issued *Pathology's Future: A View from Leaders in Health Care*, a report based on the recommendations of a panel of leaders in health care both within and outside pathology and laboratory medicine. The report highlights pathology's role in these healthcare trends: healthcare reform and economics; health information technology; patient safety and quality assurance; new diagnostic technologies; national and global public health; and patient-centered care. Download the report at [www.ascp.org/PathologysFuture](http://www.ascp.org/PathologysFuture).



## ASCP/APF/PRODS Workgroup Drafts Laboratory Medicine Management Curriculum and Competencies

At the July 2010 APC/PRODS meeting, a draft of the Laboratory Medicine Management Curriculum and Competencies was presented by the ASCP/APF/PRODS Workgroup on Laboratory Management Education for Pathology Residents. The document is available under News & Documents in the Residency Program Directors' section of the ASCP Web site: [www.ascp.org/ResidentPD](http://www.ascp.org/ResidentPD).

## Molecular Genetic Test Reports for Heritable Conditions

ASCP and RAND Health have developed an online course, "Molecular Genetic Test Reports for Heritable Conditions—Effective Communication Ensures Better Outcomes." Funded through a cooperative agreement from the Centers for Disease Control and Prevention, the online course focuses on ways to select molecular genetic tests for a particular condition or indication and discusses recommendations for disease management or prevention for the genetic conditions. In addition to pathologists and laboratory professionals, the course is designed for practicing clinicians. It is available for purchase Oct. 1, 2010. [www.ascp.org/RAND](http://www.ascp.org/RAND)

## ASCP Endorses Campaign to Develop New Antibiotics

ASCP has endorsed an initiative to develop 10 new antibacterial drugs by the year 2020. Antibiotics lose their effectiveness over time as bacteria develop resistance to the drugs. The drugs then must be used sparingly to prolong their effectiveness, challenging physicians in their attempts to treat infectious diseases. As a result, pharmaceutical companies are withdrawing from antibiotic drug research and development. "The 10 x '20 Initiative," a campaign of the Infectious Diseases Society of America, aims to reverse these trends by creating a research and development enterprise to produce 10 new antibiotics by the year 2020. Read more at [www.ascp.org/10by20](http://www.ascp.org/10by20).

## ASCP and Siemens to Award \$185,000 in Scholarships in 2011

ASCP is partnering with Siemens Healthcare Diagnostics to award \$185,000 in scholarships to clinical laboratory students. The purpose of these scholarships is to help defray education costs, promote medical laboratory science as a rewarding career, and address the shortage of qualified professionals. The deadline to apply is Nov. 15, 2010. Early applicants will be entered in a contest to win a \$50 gift card. Visit [www.ascp.org/scholarships](http://www.ascp.org/scholarships) for full details.



## ASCP Celebrates Membership Anniversaries

This year, more than 3,000 pathologists and laboratory professionals are celebrating their five-, 10-, 25- or 50-year anniversaries as members of ASCP. The number of five-year members is 1,175; 10-year members, 1,472; 25-year members, 389; and 50-year members, 95. On behalf of the ASCP Board of Directors, the entire staff and nearly 130,000 members worldwide, thank you for your long-standing membership and commitment to the profession of pathology and laboratory medicine.

## ASCP Honors 47 Medical Students

ASCP recently honored 47 second-year medical students with the Academic Excellence and Achievement Award. ASCP annually honors one student, who is nominated by their Department Chair, at each medical school in the United States, Canada, and Puerto Rico. The purpose of this award is to encourage superior academic performance and to recommend a rewarding career in pathology to the highest caliber candidates. Read more at [www.ascp.org/47MedicalStudents](http://www.ascp.org/47MedicalStudents).

## The 2010 ASCP National Student Honor Award Winners

ASCP announces the recipients of the Society's 2010 National Student Honor Awards. The award recognizes excellent students in the laboratory professions. To receive the award, applicants must be student members of ASCP, have a minimum GPA of 3.3 on a 4.0 scale, and demonstrate leadership and community service activity participation. See the list of award recipients. Read more at [www.ascp.org/NSHAs](http://www.ascp.org/NSHAs).

## Michele D. Raible, MD, PharmD, FASCP, 1956–2010

Michele D. Raible, MD, PharmD, FASCP, member of ASCP since 1994, passed away on June 21, 2010, while undergoing treatment for leukemia. Dr. Raible was an active member of PRODS, the Pathology Residency Program Directors Section of the Association of Pathology Chairs. She served as deputy head of pathology at the University of Illinois at Chicago. Dr. Raible was deeply committed to the laboratory profession and to the vision of the Oakland University William Beaumont School of Medicine in Rochester, MI. Read more at [www.ascp.org/MITN](http://www.ascp.org/MITN).

## New ASCP Resident Handbook Available

The new ASCP Resident Handbook is now available. The booklet includes information regarding ASCP membership, volunteer opportunities, educational programs, publications, and other valuable resources for residents. Download the book at [www.ascp.org/ResidentHandbook](http://www.ascp.org/ResidentHandbook).



## ASCP Urges Reform of Medicare Anatomic Pathology Self-Referral Rules

ASCP met in June with several senior officials at Centers for Medicare and Medicaid Services (CMS) to discuss anatomic pathology self-referral schemes. ASCP, joined by the American Clinical Laboratory Association, several independent clinical laboratories, and the College of American Pathologists, noted the widespread abuse of the Stark In-Office Ancillary Services (IOAS) exemption by physicians who are profiting on the pathology services they order. The coalition pressed CMS to remove anatomic pathology services from the exemption, which excludes certain physician services, such as laboratory tests and anatomic pathology services, from the law's prohibition on self-referral.

# MAKING HEADLINES

## Holladay Discusses Future of Pathology and Lab Medicine in MLO

ASCP Executive Vice President E. Blair Holladay, PhD, SCT(ASCP)<sup>CM</sup>, wrote about healthcare reform, comparative effectiveness research, and the future of pathology and laboratory medicine in the July 2010 issue of *Medical Laboratory Observer*.

[www.mlo-online.com/features/2010\\_july/0710\\_62.aspx](http://www.mlo-online.com/features/2010_july/0710_62.aspx)

## The Progressive Features ASCP President on Gene Patents

ASCP President Mark H. Stoler, MD, FASC, discussed the negative impact of gene patents in an article called "Patently Unjust," published in the June issue of *The Progressive*.

[www.ascp.org/Newsroom#Progressive](http://www.ascp.org/Newsroom#Progressive)

## Katz Highlighted in Wall Street Journal/Health Blog

ASCP Teleconference presenter Louis M. Katz, MD, was highlighted in a June 14 *Wall Street Journal* health blog article, "Chronic Fatigue Sufferers May Be Asked to Avoid Donating Blood." Dr. Katz's June 11 ASCP Teleconference examined xenotropic murine leukemia virus-related virus (XMRV)—a retrovirus that some researchers believe may be responsible for chronic fatigue syndrome.

[www.ascp.org/MITN#Katz](http://www.ascp.org/MITN#Katz)

## Finn Discusses Lab Automation with San Bernardino Sun

ASCP board member William G. Finn, MD, FASCP, discussed lab automation and the continued need for laboratory professionals to perform new, specialized tests, in an article in the June 23 *San Bernardino Sun*. [www.ascp.org/MITN#Finn](http://www.ascp.org/MITN#Finn)

## 2010 ASCP ANNUAL MEETING

Registration is available on site for the 2010 ASCP Annual Meeting, October 27–31, in San Francisco. Dr. Harald zur Hausen, 2008 Nobel Laureate, will present the keynote address, "Search for Infectious Agents in Human Cancers." The ASCP Leadership Exchange for laboratory managers and supervisors is an integral part of the 2010 meeting.

[www.ascp.org/2010AnnualMeeting](http://www.ascp.org/2010AnnualMeeting).

## 2010 ASCP Awards

ASCP will honor several individuals with awards and Masterships at the 2010 ASCP Annual Meeting in San Francisco this October.

The **President's Award** goes to Fred Silva, MD, FASCP.



Silva

**ASCP Masterships** will be bestowed on Henry D. Appelman, MD, FASCP; Wendy L. Arneson, MS, MT(ASCP); John R. Ball, MD, JD; Freida L. Carson, PhD, HT(ASCP); Yener S. Erozan, MD, FASCP; Cynthia Johns, MSA, MLS(ASCP)<sup>CM</sup>SH<sup>CM</sup>; Robert W. McKenna, MD, FASCP; and Cynthia E. Wilkerson, CDR, MSC, USN, MT(ASCP).



Appelman



Arneson



Ball



Johns



McKenna



Carson



Wilkerson

## Ward Burdick Award for Distinguished Service to Pathology:

Wayne W. Grody, MD, PhD, FASCP



Grody

## HP Smith Award for Distinguished Pathology Educator:

John R. Krause, MD, FASCP



Krause

## Israel Davidsohn Award for Distinguished Service:

E. Eugene Baillie, MD, FASCP



Baillie

## Member Excellence in Education Award:

Karen A. Brown, MS, MLS(ASCP)<sup>CM</sup>



Brown

## Member Excellence in Management Award:

Susan F. Kozlowski, MSA, MT(ASCP)SBB,DLM



Kozlowski

## Member Lifetime Achievement Award:

John R. Snyder, PhD, MT(ASCP)SH



Snyder

## 2011 ASCP ANNUAL MEETING

The ASCP 2011 Annual Meeting/WASPaLM XXVI World Congress, will be held October 19–23, 2011, in Las Vegas. The meeting debuts an exciting event for education and collegial exchange among members of the entire laboratory team. Visit [www.ascp.org/2011AnnualMeeting](http://www.ascp.org/2011AnnualMeeting) for details.







Wong

# Genome Sequencing as

By Bang Wong, MS, MA

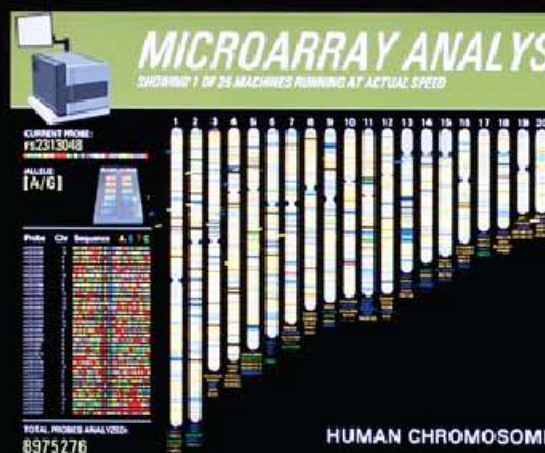
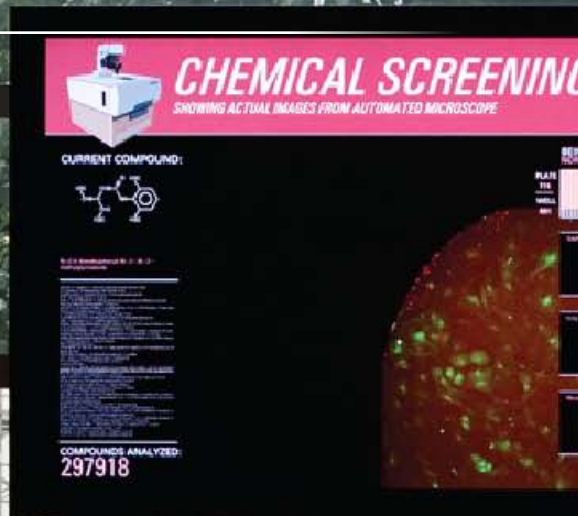
**R**esearch institutions have a responsibility to inform the public about science happening today. At the Broad Institute in Cambridge, MA, research focuses on deciphering all the information encoded in the human genome, and understanding human genetic variation and its role in disease. To communicate this work to the public, the Broad Institute has created the DNATrium in its Main Street lobby on the campus of the Massachusetts Institute of Technology (MIT).

One of the exhibits in the DNATrium is the DataStream. The Broad makes much of the data it collects publicly available. We present those data on large displays,

essentially streaming it onto the street. What makes this exhibit unique is that it shows real data and provides the public with a rare chance to see raw data. The panels show data from genome sequencing, genetic analysis, and chemical screening.

DNA is sequenced by labeling each of the letters of DNA with a different color dye. When the DNA molecule moves past the detector, this sequence of color is read. In this way, 3.5 billion letters of the human genome were sequenced.

The Data Stream displays the work of one machine able to process 96 samples. In the upper right of the Genome







# Public Art

Sequencing Panel is an enlargement of one of those chromatographs. Here it shows the entire sequence of the rabbit, estimated to be 2.7 billion letters long. It takes many machines working around the clock to complete such a project. Because the DataStream shows real data, mistakes such as misloaded lanes or failed reactions are visible. The quality of the data (visible by the sharpness of the peaks in the closeup) is also laid bare. We think it is important to show that science can be imperfect and downright messy.

For more on the DNATrium, see [www.broadinstitute.org/outreach/dnatrium/dnatrium](http://www.broadinstitute.org/outreach/dnatrium/dnatrium)

*Mr. Wong is the Creative Director of the Broad Institute of the Massachusetts Institute of Technology and Harvard University, and an Adjunct Assistant Professor in the Department of Art as Applied to Medicine at the Johns Hopkins University School of Medicine. His work focuses on communicating science visually in the areas of scientific graphics, data visualization, and art and design. Mr. Wong earned a master's degree in immunology in 1999 and a master's degree in medical and scientific illustrations in 2001, both from the Johns Hopkins University School of Medicine. [www.bangwong.com](http://www.bangwong.com)*



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